REMARKS

Applicant has filed a CPA and further amended the claims in order to more particularly define the invention taking into consideration the Final Rejection and the interview granted the undersigned attorney by the Examiner in charge of this application.

Claims 16 to 38 have been canceled from the application and replaced with claims 39 to 61. Applicant most respectfully submits that all the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing the particularly point out and distinctly claim the subject matter which Applicant regards as the invention has been carefully considered. Applicant wishes to emphasize that the level of one of ordinary skill in the art must be taken into consideration when evaluating the language of the claims. It is against this background that the claims need to be considered not only for compliance with 35 U.S.C. 112 but also with respect to the prior art.

The claims have been rewritten as noted and in rewriting the claims, the specifically objected to terminology has been avoided. Proper Markush language has been used in the claims and it is most respectfully requested that this aspect of the rejection be withdrawn.

The Official Action finds the expression "monoglyceride preparation" unclear in the claims. Applicant wishes to note that the complete expression used in the claims is "monoglyceride preparations having at least 80% monoglyceride content".In this regard, Applicant most respectfully directs the Examiner's attention to specification, page 4, line 30 to page 5, line 4 which explains what this expression covers, namely

> In a monoglyceride the acyl chain is normally in the R1 or R3 position. However, there is normally a acyl migration between the 1 and 2 carbons in the glycerol molecule resulting in approximately 90% is in the R3 position and 10% in the R2 position. Thus, in the present invention distilled 1-monoglycerides from Danisco Ingredients (Denmark) with a purity of more than 80% preferably more than 90%, more preferably over

> 95% is used. The diglyceride content is maximum 3% and triglycerides and fatty acid content is less than 1.0%. The monoglycerides according to the invention normally contains more than 80% of a specific fatty acid, preferably over 90%.

Applicant most respectfully submits that one of ordinary skill in the art would clearly understand the expression used and therefore it is most respectfully requested that this aspect of the rejection be withdrawn.

Applicants have not used the structural formula for the fatty acid as previously presented. As discussed during the interview, the structural formula was not consistent with the present of an unsaturated bond. The description of the fatty acid is fully supported by applicant's specification. Also new claims 39 and 54 specify that the percentage of monoglyceride a) in fatty acid b0 is between 10 and 90% as fully supported by Applicant's specification at page 7 lines 17-22.

However, if the Examiner has any further suggestions for amending the claims to overcome the rejection, then please contact the undersigned attorney so that acceptable claim language can be worked out in an effort to expedite the prosecution to an early allowance.

The anticipation rejections under 35 USC 102 set forth in items 4 and 5 on page 3 of the Official Action has been carefully considered but is most respectfully traversed in view of the amendments to the claims adding the limitation wherein the percentage of monoglyceride a) in fatty acid is between 10 and 90%.

With respect to EP 0544612, applicant wishes to point out that EP 0544612 discloses in the claims a composition based on a triglyceride in contrast to the present invention which is based on a combination of a monoglyceride and a fatty acid in the amounts specified.

Furthermore, in all the examples described in EP 0544612, the actual composition used is based on a gelatine capsule into which the immunogen has been entrapped and which subsequently has been subjected to an enteric coating using soy bean oil or a triglyceride.

Therefore, it is most respectfully submitted that neither the formulation process or the actual pharmaceutical agents used in EP 0544612 disclose anything that

resembles the present invention. Accordingly, it is most respectfully requested that this rejection be withdrawn.

With respect to WO 93/06921, Applicant wishes to point out that WO 93/06921 discloses colloidal particles based on monoglycerides and a "fragmenting agent". Also disclosed is a very extensive description of the physical chemical background of all lipid-based phase systems that are known today. This thorough description is also seen in the patent claims and it is Applicant's opinion that the invention that is described in the reference covers the entire field of lipid-based pharmaceutical agents, including all inventions that has already been approved around the world. It could be looked upon as a textbook of the lipid based systems known in the literature today.

Thus, it is surprising that WO 93/06921 does not disclose the actual formulation, which the present invention is based upon (a monoglyceride and a fatty acid) except incidently at page 20 which disclosure has been obviated by the further amendment to the claims which specify wherein the percentage of monoglyceride a) in fatty acid b0 is between 10 and 90%. Therefore the claimed formulation based on a monoglyceride and a fatty acid is in fact an invention, since this formulation has never been described in the prior art. That is, the invention is not described in the sense of 35 USC 102 in the reference.

In addition, as mentioned above, WO 93/06921 discloses the use of fragmenting agents in order to make dispersions of the formulation. No such procedure is necessary according to the present invention since the suspensions are formed directly in a pharmaceutically acceptable buffer system.

Furthermore, WO 93/06921 discloses, as examples of fragmenting agents, synthetic detergents such as poloxamers (Pluronic®), whereas the present invention uses a substance, which is a naturally occurring biochemical substance of mammals (a fatty acid).

Accordingly, Applicant most respectfully submits that neither the formulation process or the actual pharmaceutical agents used in WO 93/06921 anticipate the presently claimed invention.

Finally, Applicant states for the record that Applicant is well aware that the pharmaceutical agents used in the present invention are well known to everyone, even to those not skilled in the art. Furthermore, both of the agents have been used for decades in the pharmaceutical as well as in food industry as detergents or surfactant systems. In fact, the annual production of monoglycerides in the food industry exceeds 350.000 metric tons.

Thus, it is even more surprising that no one has seen the possibility of combining these two well known agents in order to achieve a simple system with well-characterized substances and which both are naturally synthesized and metabolized in mammals. Accordingly, it is most respectfully requested that the anticipation rejections be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,
BACON & THOMAS, PLLC

By: Richard E. Fichter
Richard E. Fichter
Registration No. 26,382

625 Slaters Lane, 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

REF:kdd
A02.wpd

February 20, 2001